## REMARKS

Claim 1 has been objected to for the reasons set forth at the top of page 2 of the Examiner's Office Action letter. Since claim 1 has been amended to eliminate the inadvertency referred to by the Examiner, it is believed that this objection has been eliminated.

Claims 1-13 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Seo et al. (WO 03/033593) in view of Li et al. (Polymer , 39, pp 4421-4427 (1998). This rejection is respectfully traversed.

The present invention is directed to biodegradable branched polylactide derivatives having hydrophilic functional groups and carboxy groups at each branch to form polymeric micelles of the polylactic acid derivative which possesses increased stability. Advantageously, the biodegradable branched polylactic acid derivatives of the present invention are effective in enhancing poorly water-soluble drug delivery systems.

As clearly described in the background art of the present application, solubilization of poorly water-soluble drugs is an essential requirement for delivering such drugs into the body. To achieve this result, polymeric micelles used for solubilizing poorly water-soluble drugs are required to be very stable, for which the critical micelle concentration (CMC) should be low. Micelles are in finely dispersed form when in solutions since poorly water-soluble drug solutions are contained in the droplet. Thus the method for forming micelles to solubilize poorly water-soluble drugs is regarded as most preferable and thus, among the solubilization methods using micelles, the use of a surfactant is one of the key technologies.

The polylactic acid derivatives of the Seo et al. reference have a linear structure in which only one molecule of a carboxyl group is bound to the terminal location and thus the molecular weight of the polylactic acid derivatives capable of forming polymeric micelles in aqueous solution is limited to the range of 2000 Daltons or less. In other words, polylactic acid derivatives having one carboxyl terminal group and a higher molecular weight than 2000 Daltons could not form micelles since they could not be dissolved well in an aqueous solution. Therefore the polylactic acid derivatives of the Seo et al. reference must have a relatively low molecular weight and accordingly would fail to entrap the drug in the micelle for a long time due to poor stability of the formed micelles.

The Li et al. reference discloses star-block copolymers which are clearly distinguished from the present polylactic acid derivatives in their chemical structure. Furthermore, from Li et al's copolymer, microparticles or hydrogels are formed which result in a film form (See Introduction, p. 4425, left column, p. 4426 left column, "swell" of the Li et al reference). Therefore, the copolymer of the Li et al. reference is clearly distinguished from the present polylactic acid derivative which forms micelles as defined with the present invention. Furthermore, the Li et al. reference discloses that its copolymer provides a uniform environment to the entrapped drug through biphasic degradation and after completing the release of the drug, the polymer matrix is rapidly removed (See p. 4426, both columns). However, according to the present invention, the polylactic acid derivative forms micelles in an aqueous solution in order to entrap the drug in the micelles and administer it in micelle form. Also, the copolymer of the Li et al. reference has a structure of 4- or 8-PEG armed PLLG polymer. In Li et al's copolymer PEG is introduced for the balance with the hydrophobicity from PLLG. By the incorporation of PEG arms, the hydrophilicity of the resulting copolymer increases. In such a constitution of using hydrophilic PEG arms for the balance with the hydrophobic moiety, there is the problem in that the molecular weight of the PLLG would increase according to the increase in hydrophilicity. However, according to the present invention, in the polylactic acid derivative, polymer parts are bound to a small, single molecule. That is, no hydrophilic PEG is introduced therein and thus the hydrophilicity of "R" in formula (1) can be maintained. In addition, polymers containing PEG, such as that of the Li et al. reference, are very expensive and thus difficult to commercialize. On the other hand, the polylactic acid of the present invention does not contain such an expensive PEG moiety and thus can be used in preparing a drug-delivery system in a very economical manner.

Accordingly, the polylactic acid derivative of the present invention is clearly distinguishable from that of the Li et al. reference in its polymer structure and in the properties due to its structural difference when compared to the prior art reference. The Li et al. reference does not teach or suggest the present polymer structure and the property of forming micelles in an aqueous solution therefrom. Furthermore, as referred to hereinabove, according to the present invention, the drug delivery systems can be prepared in a very economical manner. Such

advantageous results cannot be expected from the Li et al. reference which essentially uses PEG, which is very expensive.

Conclusion

Accordingly, in view of the above amendments and remarks, it is believed that the Applicants have defined an inventive contribution which is not contemplated by any reference relied on by the Examiner, either alone or in combination. Accordingly, reconsideration of the rejections and allowance of all of the claims is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Joseph A. Kolasch, Reg. No. 22,463, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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